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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Nadejda G Gurskaya

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9951

7590

07/06/2007

B. Todd Patterson
Moser, Patterson & Sheridan
3040 Post Oak Blvd.
Suite 1500
Houston, TX 77056

EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

07/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,629	Applicant(s) GURSKAYA ET AL.	
	Examiner Maryam Monshipouri	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24-33 is/are pending in the application.
4a) Of the above claim(s) 8-10, 15-17, 26-28 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-7, 11, 14, 18, 21 and 31-33 is/are rejected.
- 7) ☒ Claim(s) 3, 24, 25 and 29 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>filed 7/2004</u> . | 6) <input checked="" type="checkbox"/> Other: <u>see attachment 1-2</u> |

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Applicant's response to supplemental restriction of elected claims 1-7, 11, 14, 18, 21, 24-25 and 29 and 31-33, filed 5/15/2007 is acknowledged. Applicant elected the species for DNA encoding SEQ ID NO:2 with E222G mutation further comprising V11I, F64L, K101E and T206A and SEQ ID NO:12 with traverse. In traversal of the original restriction requirement applicant provided same arguments dealt with in office action dated 3/2/2007. Therefore, said arguments are not addressed again and restriction remains for reasons of record.

DETAILED ACTION

Claims 1-7, 11, 14, 18, 21, 24-25, 29, 31-33, SEQ ID NO:2 variant having E222G and SEQ ID NO:12 are under examination on the merits. Claims 8-10, 12-13, 15-17, 19-20, 26-28, 30 are hereby withdrawn as drawn to non-elected invention. Claims 22-23 are canceled.

Claim Objections

Claims 14, 21, 31-32 are objected to because of the following informalities: Said claims depend from polypeptide claims, which are drawn to non-elected subject matter. Applicant is required to rewrite said claims. Appropriate correction is required.

Claims 1-3 are objected to because of the following informalities: said claims still recite non-elected subject matter. Applicant is advised to delete non-elected subject matter from said claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "the" in claims 21 and 31 lacks antecedent basis.

Claims 14, 21 and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "production" in all said claims, is confusing because it is unknown whether the methods utilize DNA or polypeptide. Further, no active step is recited in said claims. Passive terms such as "production" should be substituted by another term/phrase such as "recombinantly producing" or "recombinantly expressing" etc. to render the claims more clear. Appropriate correction is required.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "functional" in claim 33 is vague. It is unclear what function applicant is referring to. If applicant by using said term is referring to the fluorescent properties, she/he must specifically recite said function into the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 4, 6 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Inouye et al. (FEBS Letters, 341, 277-280, 1994, cited in the IDS). Inouye teaches a DNA sequence encoding a genetically engineered mutant of SEQ ID NO:2, with at least one substitution and position 222 (i.e. E222G) as well as some others, wherein said mutant has fluorescent properties, and displays 94.4% identity to SEQ ID NO:2 (see the attached sequence alignment) anticipating claim 1. Since sequence alignment results are dependent on alignment parameters and 94.4% is very close to 95% it is believed that by changing the alignment parameters Inouye's sequence can be shown to encode a polypeptide sequence having 95% identity to SEQ ID NO:2, anticipating claim 33. In page 278, Inouye teaches about expression vectors and cassettes comprising its DNA and host cells (i.e. E. coli) comprising said cassettes, anticipating claims 4 and 6.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-7, 11, 14, 18, 21, 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Stubbs et al. (U.S. Patent No. 6,919,186, issued 7/2005). Stubbs teaches a DNA sequence (see its SEQ ID NO:1) encoding a genetically engineered mutant of SEQ ID NO:2, with at least one substitution and position 222 (i.e. E222G), F64L, and T206 as well as some others, wherein said mutant has fluorescent properties, and displays 93.7% identity to SEQ ID NO:2 (see the attached sequence alignment) anticipating claims 1-2. Since sequence alignment results are dependent on alignment parameters and 93.7% is very close to 95% it is believed that by changing the alignment

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parameters Inouye's sequence can be shown to encode a polypeptide sequence having 95% identity to SEQ ID NO:2, anticipating claim 33. In columns 8-9 Stubbs teaches about vectors (expression cassettes) and host cells comprising its DNA sequences, anticipating claims 4-7, 11, 18. In column 4, Stubbs teaches about methods of detecting gene expression utilizing DNA sequences encoding variants of SEQ ID NO:2, anticipating claims 14 and 21.

Allowable Subject Matter

Claims 3, 24, 25, 29 (directed to SEQ ID NO:12 species only) are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This is because DNA encoding SEQ ID NO:12 is free of prior art. Further the prior art does not teach or suggest preparing such specifically claimed DNA sequence. Hence said sequence is also non-obvious. Since said DNA sequence is both novel and non-obvious, expression cassettes, and host cells comprising said sequence and a methods of use of said sequence is also novel and on-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

re. ~~conshi~~
Maryam Monshipouri Ph.D.

Primary Examiner
